

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



10/528851



(43) International Publication Date
22 April 2004 (22.04.2004)

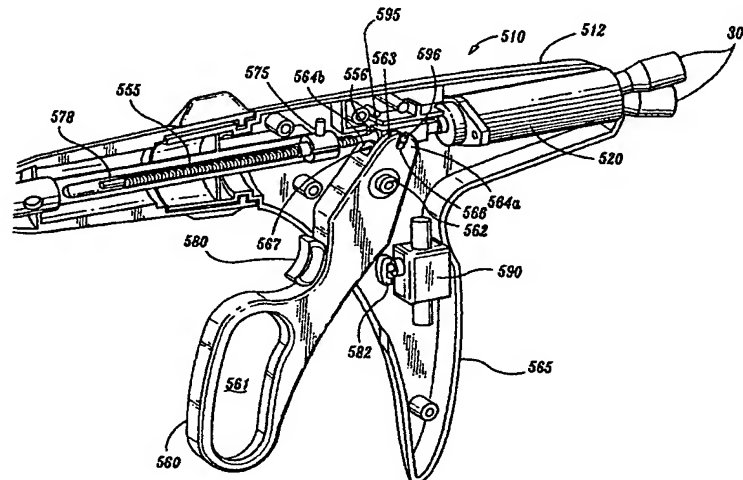
PCT

(10) International Publication Number
WO 2004/032760 A2

- (51) International Patent Classification⁷: **A61B 17/068**
- (21) International Application Number:
PCT/US2003/031651
- (22) International Filing Date: 6 October 2003 (06.10.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/416,094 4 October 2002 (04.10.2002) US
- (71) Applicant (for all designated States except US): **TYCO HEALTHCARE GROUP, LP** [US/US]; 150 Glover Avenue, Norwalk, CT 06859 (US).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): **ROY, Philip, C.** [US/US]; 1680 Shepard Avenue, Hamden, CT 06518 (US).
- (74) Agent: **AUDET, Paul, R.**; US Surgical, A Division of Tyco Healthcare Group, LLP, 150 Glover Avenue, Norwalk, CT 06856 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— without international search report and to be republished upon receipt of that report

[Continued on next page]

(54) Title: PNEUMATIC POWERED SURGICAL STAPLING DEVICE



(57) Abstract: A surgical stapler which includes or onto which a tool assembly can be mounted for deforming a plurality of surgical fasteners through and fastening tissue includes a housing having a fixed handle and a clamping handle mountable to the housing. The clamping handle is selectively movable relative to the fixed handle from a first position in spaced relation relative to the fixed handle to a second position closer to the fixed handle to actuate the clamping of tissue. An adapter yoke is included which translates within the housing upon actuation of the clamping handle. The adapter yoke mechanically cooperates with a lead screw to actuate the tool assembly to clamp tissue. A drive assembly is also included for rotating a shaft which mechanically engages the lead screw. Upon selective activation of the drive assembly, the shaft rotates the lead screw to advance a roll nut and force a firing piston into the tool assembly to deform the surgical fasteners through and fasten the tissue.

WO 2004/032760 A2

WO 04/032760 A2



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PNEUMATIC POWERED SURGICAL STAPLING DEVICE

CROSS REFERENCE TO RELATED APPLICATION:

This application claims priority from of U.S. Provisional Application Serial No. 60/416,094 filed on October 4, 2002 by Philip C. Roy entitled "PNEUMATIC SURGICAL STAPLING DEVICE", and incorporates its entire contents by reference herein.

BACKGROUND

Technical Field

The present disclosure relates to surgical staplers for implanting mechanical surgical fasteners into the tissue of a patient, and, in particular, to surgical staplers which are pneumatically powered to fire surgical fasteners into tissue.

Background of Related Art

Surgical staplers which implant surgical fasteners into tissue using the force of pressurized gas are known in the art. The majority of these instruments utilize a pressurized air supply which connects to a trigger mechanism by way of an intricate series of hoses and actuators. The trigger mechanism, when depressed, simply releases pressurized gas to implant a fastener into tissue.

Current known devices can typically require 10-60 pounds of manual hand force to clamp tissue and deform surgical fasteners through tissue which, over repeated use, can cause fatigue.

It would be desirable to provide a low cost pneumatic motor or reciprocator which couples to a pressurized gas supply (disposed either internally or externally relative to the surgical stapler) and provides the needed energy required to fire the instrument to form a series of surgical fasteners into and through tissue. It would also be desirable to provide an ergonomically advanced surgical stapler which reduces fatigue during repeated use and provides the surgeon with more tactile feedback during activation of the stapler.

SUMMARY

The present disclosure relates to a surgical stapler having a distal end onto which a tool assembly having a pair of opposing tissue engaging surfaces can be mounted for deforming a plurality of surgical fasteners through tissue to fasten tissue. The stapler includes a housing having a fixed handle which extends therefrom. A clamping handle is mounted to the housing and selectively movable relative to the fixed handle from a first position in spaced relation relative to the fixed handle to a second position closer to the fixed handle to actuate the clamping of tissue. Advantageously, an adapter yoke is included which translates within the housing upon actuation of the clamping handle. The adapter yoke mechanically cooperates with a lead screw to

actuate the tool assembly to clamp tissue. The stapler also includes a drive assembly having a shaft which is mechanically engaged with the lead screw. Upon selective activation of the drive assembly, the shaft rotates the lead screw to advance a roll nut distally along the lead screw to force a firing piston into the tool assembly when mounted on the housing to deform the surgical fasteners through the tissue to fasten the tissue.

Preferably, the drive assembly is pneumatically powered and includes a pressure sensitive trigger which is selectively variable to regulate the advancement of the roll nut along the lead screw which, in turn, regulates the speed at which the surgical fasteners are deformed. Advantageously, the stapler includes at least one safety which prevents activation of the drive assembly until the safety is deactivated. In one embodiment according to the present disclosure, the safety is automatically deactivated when the clamping handle is moved to the second position to clamp tissue. Preferably, one of the safeties is a firing safety which prevents the roll nut from advancing to force the firing piston until the firing safety is deactivated.

In another embodiment according to the present disclosure, the shaft rotates upon activation of the drive assembly which in turn rotates the lead screw. Preferably, the stapler includes a switch for reversing the rotation of the shaft of the drive assembly upon activation thereof.

The present disclosure also relates to a stapler having a housing with an elongated member attached thereto and a tool assembly which is attached to the distal end of the elongated member. The tool assembly includes opposing tissue engaging surfaces and a plurality of surgical fasteners. The stapler also includes a selectively activatable drive assembly having an actuation shaft which is mechanically engaged with a lead screw. Upon selective activation of the drive assembly, the actuation shaft rotates the lead screw to advance a firing shaft and actuate the tool assembly to initially clamp tissue between opposing tissue engaging surfaces of the tool assembly and subsequently to force a firing piston into the tool assembly to deform the surgical fasteners through tissue to fasten tissue.

In one embodiment of the present disclosure, the actuation shaft reciprocates upon activation of the drive assembly. The actuation shaft, in turn, is mechanically engaged with a converter which converts the reciprocal motion of the actuation shaft into rotary motion of the lead screw.

In yet another embodiment according to the present disclosure, the stapler includes a canister for containing a supply of pressurized gas for activation of the drive assembly. Preferably, the canister is internally disposed within the housing. Advantageously, the canister is selectively replaceable.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the subject instrument are described herein with reference to the drawings wherein:

Fig. 1A is a schematic, side view with portions broken away of a surgical stapler according to the present disclosure having a pneumatically-powered rotary drive assembly for forming fasteners;

Fig. 1B is a schematic, side view with portions broken away of an alternate embodiment of a tool assembly for use with the stapler of Fig. 1A;

Fig. 2 is a schematic, side view with portions broken away of an alternate embodiment of the pneumatically-powered surgical stapler according to the present disclosure having a reusable canister externally attached thereto;

Fig. 3 is a schematic, side view with portions broken away of a surgical stapler according to the present disclosure having a pneumatically-powered reciprocating drive assembly for forming fasteners;

Fig. 4 is a schematic, side view with portions broken away of a surgical stapler according to the present disclosure having a pneumatically-powered reciprocating drive assembly for forming fasteners and an internally-disposed canister;

Fig. 5A is side, perspective view removed and portions broken away of another embodiment according to the present disclosure showing a manual clamping

handle for clamping tissue in a pre-clamped position and a pneumatic trigger shown disengaged from a safety valve for firing the stapler;

Fig. 5B is a side, perspective view of the embodiment of Fig. 5A which shows the clamping handle in a clamped position and the pneumatic trigger in an engaged position with the safety valve for activating the pneumatic motor to fire fasteners; and

Fig. 6 is a schematic, exploded view of an adapter yoke which connects to the drive assembly.

DETAILED DESCRIPTION

Referring initially to the embodiment disclosed in Figs. 1A and 1B, a surgical stapler 10 is shown having a pneumatically-powered rotary drive assembly here shown as including a pneumatic motor 20. It is envisioned that the presently disclosed drive assembly 20 can be utilized with any type of known surgical stapler. As such, a general surgical stapler 10 is schematically depicted in the drawings and described herein. For example, stapler 10 includes a housing 12 having an elongated member or shaft 30 attached thereto. Shaft 30 includes a proximal end 32 which attaches to a distal end 21 of the housing 12 and a distal end 34 which operatively couples to a tool assembly or end effector 100. Tool assembly 100 depicted in Fig. 1A is a conventional longitudinal stapler having opposing tissue contacting surfaces 110 and 120 and tool assembly 200 depicted in Fig. 1B is that of a conventional circular stapler (not shown) having opposing tissue contacting surfaces 210 and 220. For the purposes herein,

stapler 10 will be described as having tool assembly 100 attached to distal end 34 thereof.

Housing 12 includes a fixed handle 65 which is generally formed like a pistol grip to enhance manipulation of the stapler 10 as needed during surgery. Stapler 10 may also include a movable handle actuator 60 (shown in phantom) which is movable relative to fixed handle 65 (in the direction of arrow "A") to actuate opposing tissue contacting surfaces 110 and 120 of tool assembly 100 (See arrow "B") to manipulate, grasp fasten and cut tissue. The proximal end of shaft 30 is integrally associated with or selectively attachable to housing 12, handle 65 or one or more actuating assemblies (not shown) of a manual (or other, e.g., robotic or computer operated) open or endoscopic surgical stapler 1 (or system - not shown). Many types of mechanical actuators and handle mechanisms are known which are configurable to communicate with and actuate the functions of tool assembly 100.

As best seen in Fig. 1A, a staple deformation or staple firing mechanism 70 and knife assembly 75 may also be included in distal end 34 of the shaft 30 and/or included with tool assembly 100. It is contemplated that the same or additional actuating mechanisms may be employed to drive staple firing mechanism 70 and knife assembly 75. For example, Figs. 5A and 5B show one embodiment of a surgical stapler 510 which includes a clamping handle 560 which cooperates with tool assembly 100 to grasp tissue while a separate motor drives staple firing mechanism 70 and knife assembly 75 through tissue.

Fig. 1A shows one embodiment of a stapler 10 which includes a simple, low cost rotary pneumatic drive assembly 20 housed within surgical stapler 10 to actuate a firing shaft 55 which, in turn, cooperates with tool assembly 100 to clamp tissue between tissue engaging surfaces 110 and 120 and to drive a plurality of surgical fasteners 350 through tissue. Surgical stapler 10 is preferably, as shown, designed for one-handed operation by the user and requires minimal trigger force to deform the surgical fasteners 350 through tissue. In other words, stapler 10 is designed such that pneumatic drive assembly 20 actuates and controls the high-force portion of the activation sequence (i.e., the so-called "firing stroke") thus alleviating user fatigue and allowing simple, consistent and repeated use of the stapler during surgery.

Actuation of pneumatic drive assembly 20 rotates a motor shaft 22 which, in turn, translates a firing shaft 55 which initially closes opposing tissue contacting surfaces 110 and 120 and subsequently forces staple firing mechanism 70 and knife assembly 75 through tissue to sequentially fasten and separate the tissue. It is envisioned that pneumatic drive assembly 20 may cooperate with a clamping handle 60 which clamps tissue between surfaces 110 and 120 while pneumatic drive assembly 20 operates to drive firing shaft 55. A series of gears, shafts, screws or other mechanisms may be employed to convert the rotational pneumatic energy from pneumatic drive assembly 20 to firing shaft 55 to actuate tool assembly 100. Air or other pressurized gas is preferably externally supplied, e.g., through a pneumatic air hose 68, 68a, from a hospital's existing pneumatic air or gas supply 300, e.g., pressurized gas outlet, to run

pneumatic drive assembly 20. Alternatively, as shown in Fig. 4, a self-contained or rechargeable gas supply 405 may be disposed in the surgical stapler 10 and be operatively connected to activate pneumatic drive assembly 20.

Preferably, stapler 10 also includes a trigger, here, a movable pressure trigger 80, which activates the supply of pressurized gas to fire stapler 10. It is envisioned that trigger 80 may include a regulator 90 which controls the amount of pressurized gas to pneumatic drive assembly 20 to fire shaft 55. As such, by selectively squeezing trigger 80, the user can control the initial grasping of the tissue with the opposing tissue contacting surfaces 110, 120 of tool assembly 100 and subsequently control the firing force of stapler 10 through the tissue. The further, faster or harder that trigger 80 is squeezed, the faster pneumatic drive assembly 20 turns, thus making stapler 10 fire more quickly and/or making the stapler fire with more power. Moreover, it is contemplated that trigger 80 may include a series of graduations, incremental stops or a ratchet mechanism (not shown) to regulate the pressure of the gas being supplied to drive assembly 20 based on the distance trigger 80 is depressed. A separate stop or switch (not shown) may also be included with the trigger 80 to switch the motor from a "grasping" mode to a "firing" mode. It is also envisioned that releasing trigger 80 stops the supply of pressure to the pneumatic drive assembly 20 and stops the firing stroke of stapler 10. As such, the stroke may be stopped at any time during initial grasping of the tissue or during deformation of the fasteners 350.

It is envisioned that pneumatic drive assembly 20 may also be reversible, i.e., retract the firing shaft 55 as needed and open the tissue contacting surfaces 110, 120 of tool assembly 100. Thus, directional switch 50 may be included with the pneumatic drive assembly 20 to accomplish this purpose. In Fig. 1A, direction "A" indicates forward and direction "B" indicates reverse.

Fig. 2 shows an alternate embodiment of a surgical stapler, 210, that includes an externally mounted air canister 250 which is removably attached to stapler 210. Preferably, canister 250 is selectively replaceable (or reusable) and supplies pressurized gas to operate an internally disposed pneumatic drive assembly 220 to turn shaft 222. It is envisioned that one of a series of different canisters 250 may be selectively attached to stapler 210 depending upon the type of tissue being fastened and the desired pressure range needed to properly fasten the tissue. Canister 250 may also be internally disposed within fixed handle 265 as shown in Fig. 4. Different canisters 250 may be sold as a kit and color coded for specific tissue types or size/contents. Much like stapler 10 disclosed in Fig. 1, surgical stapler 210 may also include any one or any combination of structures or operating components described above, e.g., housing 212, movable handle 80, switch 50, variable pressure trigger 280, trigger regulator 90, firing shaft, 55 staple formation mechanism 70, knife assembly 75 and/or tool assembly 100, 200. The distal end of shaft 30 can be operatively attached to a tool assembly (not shown).

Fig. 3 shows another embodiment of the present disclosure, a surgical stapler 310 which has a reciprocating pneumatic drive assembly or reciprocating motor 320 (i.e., reciprocating cylinder) coupled to a pneumatic gas supply 300 to actuate firing shaft 355. More particularly, pneumatic air supply 300 may be attached to housing 312 and internally coupled to a valve 305 which regulates the reciprocating speed of a pair of pistons 322 and 324 disposed within reciprocating drive assembly 320. An output shaft 328 from drive assembly 320 connects to a converter 345 which is employed to convert the reciprocating energy from the reciprocating drive assembly 320 to actuate (i.e., translate) firing shaft 355. It is envisioned that a series of gears (not shown) may be utilized to accomplish this purpose. Stapler 310 may also include any one or any combination of the operating components described above with respect to Fig. 1, e.g., movable handle 60, switch 50, trigger 80, trigger regulator 90, staple formation mechanism 70, knife assembly 75 and/or tool assembly 100, 200. The distal end of shaft 330 can be operatively attached to a tool assembly (not shown).

It is envisioned that one of the many advantages of this disclosure over conventional surgical fasteners is that the amount of effort required to fire stapler 10, 210, 310 is nominal. This is primarily because pneumatically driven motor 20, 220 or 320 does the majority of the work to fire the stapler 10, 210 or 310. Moreover, the unique combination of a manual clamp-up and a motorized firing and retraction stroke will also reduce user fatigue and gives the user additional positive tactile feedback during the clamping and firing strokes.

While other non-manually actuated staplers require either batteries or an external electrical power supply to assist in firing, the presently disclosed instrument utilizes an air supply 300 readily available in most operating rooms by simple connection thereto. The presently-disclosed staplers 10, 210, 310 also allows the surgeon a wide range of firing possibilities from a "slow-fire" clamping and firing stroke to a "rapid-fire" clamping and firing stroke.

As mentioned above with respect to Fig. 2, it is envisioned that an alternate embodiment of the stapler 410 (Fig. 4) may include an internally or externally mounted canister 405 which is either sold as an integral part of the stapler (for disposable staplers) or which is removably attachable to the stapler 10 (for use with a reusable or reposable stapling instrument). As shown in Fig. 4, canister 405 is selectively replaceable or rechargeable and supplies pressurized gas to operate the internal reciprocating drive assembly 420 disposed within the housing 412. It is envisioned that one of a series of canisters 405 may be selectively attachable to the stapler 410 depending upon the type of tissue being fastened and the desired pressure range needed to properly fasten the tissue. Canister 405 may be removably engaged within housing 412 and mechanically (or electro-mechanically) coupled to a valve 408 which regulates the reciprocating speed of pistons 422 and 424 disposed within the reciprocating drive assembly 420. A user can selectively regulate the reciprocating speed of firing shaft 455 by controlling the distance trigger 480 is depressed. Much like the embodiment described with respect to Fig. 3, a converter 445 may be employed to convert the reciprocating energy from the reciprocating motor 420 to actuate (i.e.,

translate) the firing shaft 455. Again, this stapler 410 may also include any one or any combination of operating components described above with respect to Fig. 1, e.g., movable handle 60, switch 50, trigger regulator 90, staple formation mechanism 70, knife assembly 75 and/or tool assembly 100, 200.

Figs. 5A and 5B show an alternate surgical stapler 510 according to the present disclosure. Stapler 510 includes a manual clamping handle 560 for use with the pneumatic drive assembly 520. More particularly, much like the aforescribed staplers 10, 210, 310 and 410, stapler 510 includes a housing 512 which contains a pneumatic drive assembly 520 which drives a firing shaft 555 to deform the plurality of surgical fasteners (not shown) when tissue is disposed between the opposing tissue contacting surfaces 110 and 120 (Fig. 1A) of tool assembly 100. Stapler 510 also includes a trigger 580 which activates the supply of pressurize gas to drive pneumatic drive assembly 520 to fire stapler 510.

Preferably, firing shaft 555 of stapler 510 is designed as a lead screw which is connected to pneumatic drive assembly 520 via an adapter yoke 595. A screw roll nut 575 threadably engages lead screw 555 such that rotary movement of lead screw 555 translates into linear movement of roll nut 575 which advances a firing piston 578. Firing piston 578 cooperates with a tool assembly, e.g., tool assembly 100 or 200, to fire and deform fasteners (not shown) through tissue disposed between opposing tissue contacting surfaces 110 and 120 of tool assembly 100. As mentioned above,

either tool assembly 100 or 200 (or another different type of suitable tool assembly) may be designed to cooperate with firing shaft 555 to drive fasteners through tissue.

As best shown in Fig. 5A, manual clamping handle 560 is mounted to housing 512 about a pivot 562 which allows the user to selectively move handle 560 relative to fixed handle 565. Handle 560 includes a grip area 561 defined therethrough which is designed to accept a user's fingers to facilitate actuation of handle 560 from a pre-clamp position wherein handle 560 is most spaced from fixed handle 565 to a series of subsequent positions wherein handle 560 is positioned adjacent fixed handle 565. Handle 560 also includes an upper or working end 563 which is preferably bifurcated into flanges 564a and 564b. Flanges 564a and 564b, in turn, define a slot 567 therein which is dimensioned to receive the adapter yoke 595. Flanges 564a and 564b include one or more cut outs or notches 566 defined therein which are designed to cooperate with a corresponding number of pins 596 which extend from adapter yoke 595. It is envisioned that the pins 596 and notches 566 enhance mechanical engagement of the adapter yoke 595 and flanges 564a and 564b to promote consistent operation of tool assembly 100 upon actuation of handle 560. Pressurized air or gas is externally supplied from a hospital's existing pneumatic air or gas supply through one or more pneumatic air hoses 300 attached to the proximal end of the stapler 510. As mentioned above with respect to Fig. 4, a self-contained or rechargeable gas supply (not shown) may be disposed in the surgical stapler 510 and be operatively connected to activate drive assembly 520.

As best seen in Figs. 5A and 5B, upon actuation of handle 560, adapter yoke 595 engages a proximal end 556 of lead screw 555 such that translational movement of adapter yoke 595 forces lead screw 555 through roll nut 575 to move the opposing surfaces 110 and 120 of tool assembly 100 from a first position wherein the opposing surfaces 110 and 120 are spaced relative to one another to a second position wherein the opposing surfaces 110 and 120 cooperate to grasp tissue therebetween. Fig. 5B shows the relative movement of handle 560 and the corresponding movement of adapter yoke 595 and lead screw 555 upon actuation of handle 560.

Fig. 6 shows a schematic representation of adapter yoke 595 of Fig. 5A and 5B which cooperates with the clamping handle 560 to translate (See arrow "D") lead screw 555 to clamp tissue as described above. More particularly, adapter yoke 595 includes a collar 598 which mechanically engages shaft 521 of the pneumatic drive assembly 520. Rotation of shaft 521 correspondingly rotates a cylinder 597 disposed within collar 598 which, in turn, rotates lead screw 555. Preferably, shaft 521 is keyed to securely fasten within a corresponding dual slot 599 defined in cylinder 597 to insure positive engagement of shaft 521 with cylinder 597 and to permit rotary movement in either direction as shown by arrow "E".

In operation, as the user actuates handle 560, adapter yoke 595 translates to force lead screw 555 through roll nut 575 which, in turn, closes the opposing surfaces 110, 120 of tool assembly 100 about tissue grasped therebetween. Roll nut 575 is held fast by a safety 576 (described below) which allows screw 555 to rotate through roll nut

575 and actuate tool assembly 100. This is known as the "clamping stroke". Adapter yoke 595 allows screw 555 to rotate therewithin, but relative linear translation between adapter yoke 595 and screw 555 remains fixed. It is envisioned that the clamping stroke may be incrementally actuated via a ratchet or other mechanism (not shown) to allow the user to slowly or incrementally grasp tissue between opposing surfaces 110 and 120 of tool assembly 100. This also enables the user to maintain tool assembly 100 in a fully actuated and clamped position about the tissue during the so-called "firing stroke".

When clamping handle 560 is fully actuated, trigger 580 is positioned for activation of pneumatic drive assembly 520 which fires surgical fasteners into the tissue. Preferably, stapler 510 is designed such that in order to activate the pneumatic drive assembly 520 to fire surgical fasteners, the clamping stroke must be fully completed, i.e., handle 560 must be fully actuated. As best shown in the comparison of Figs. 5A and 5B, once handle 560 is fully actuated, trigger 580 is positioned to abut against a trigger safety 582 mechanically associated with trigger valve 590. Activation of trigger 580 automatically depresses safety 582 and opens trigger valve 590 which activates drive assembly 520. It is envisioned that if handle 560 is not fully actuated (i.e., the clamping stroke is not completed), safety 582 will remain activated. It is only when handle 560 is fully actuated that safety 582 releases to allow activation of the firing stroke.

In addition and prior to initiating the firing stroke, a second safety 576 may be provided and need to be actuated (i.e., manually depressed or otherwise actuated) to disengage or release roll nut 575 from a fixed orientation to allow pneumatic drive assembly 520 to rotate lead screw 555 and fire piston 578 to deform surgical fasteners (See Fig. 5B). It is envisioned that safety 582 and 576 may be one in the same or safeties 582 and 576 may be designed to mechanically (or electro-mechanically) cooperate with one another to control the firing stroke.

It is envisioned that trigger valve 590 regulates the speed of drive assembly 520 which, as can be appreciated, gives the user additional control over the formation of fasteners. For example, the speed of the deformation of surgical fasteners can be selectively controlled by the user, e.g., "slow-fire" or "rapid fire", as well as the retraction speed of firing piston 578. As can be appreciated this gives the surgeon additional tactile control during the firing stroke. Moreover, it is envisioned that trigger 580 and trigger valve 590 maybe configured such that releasing trigger 580 will instantly stop firing piston 578 and maintain firing piston 578 in linear position relative to instrument shaft 530 for subsequent re-activation. Again, these configurations enhance tactile control over the firing stroke.

As mentioned above, after the clamping stroke is completed (and the safety mechanism(s) 576 (and 582, if applicable) have been deactivated), the user squeezes trigger 580 to translate firing piston 578 and deform the surgical fasteners. More particularly, trigger 580 cooperates with trigger valve 590 to regulate the

pneumatic pressure to the pneumatic drive assembly 520 which, in turn, regulates the speed of shaft 521. The speed of the rotation of shaft 521 is directly related to the speed at which lead screw 555 rotates to cause linear reciprocation of roll nut 575. As described above, trigger 580 may be incrementally activatable from a fully open position allowing full pneumatic pressure (i.e., maximum firing speed) to fully closed position (i.e., stop) thus providing additional tactile control over the firing sequence. Preferably, a variable speed, pressure sensitive trigger 580 is utilized to activate the pneumatic drive assembly 520 to drive roll nut 575 and advance and retract firing piston 578.

Roll nut 575, in turn, translates along lead screw 555 forcing firing piston 578 to deform the surgical fasteners (not shown). The drive assembly 520 continues to turn lead screw 555 to translate roll nut 575 the appropriate linear distance to complete the deformation of surgical fastener(s). It is envisioned that once the appropriate distance has been traveled and surgical fasteners are completely formed through the tissue, drive assembly 520 automatically stops signaling the user to switch drive assembly 520 to reverse and retract roll nut 575 proximally on lead screw 555. Alternatively, drive assembly 520 may automatically shift into reverse and begin retraction of roll nut 575. It is contemplated that the roll nut 575 and lead screw 555 configuration provides a simple, low friction energy conversion from rotary motion to linear motion. Drive assembly 520 may also be configured to stop once retraction of roll nut 575 has completed.

It is contemplated that roll nut 575, upon retraction, will reset back to relatively the same position as after manual clamping. Safety 576 may then re-activated (either automatically or manually) to lock roll nut 575 in a fixed orientation to allow re-actuation or release of manual clamping handle 560 and linear retraction of lead screw 555 which opens the opposing tissue contacting surfaces 110 and 120 of tool assembly 100 to release the tissue. At this point and with a reusable stapler 10, a new cartridge or single use loading unit (SULU) may be loaded and the stapler reused.

As explained above with reference to the embodiment of Fig. 1A, stapler 510 may include a 2-position switch (not shown) which controls the drive assembly 520 to allow the user to selectively advance and retract firing piston 578 as needed during surgery.

From the foregoing and with reference to the various drawings, those skilled in the art will appreciate that certain modifications can be made to the present disclosure without departing from the scope of the same. For example, the clamping handle may include a locking mechanism (not shown) which locks the handle relative to the fixed handle upon completion of the clamping stroke.

Although the presently disclosed staplers utilize a pneumatic drive assembly to drive the firing piston, it is envisioned that an electric drive assembly (not shown) may also be utilized to accomplish the same purpose. As such, similar trigger assemblies, switches and safety mechanisms may be employed to cooperate with the

electric drive assembly to advance and retract the firing piston to deform the surgical fasteners.

Preferably, the presently disclosed staplers are designed for endoscopic use and are dimensioned to fit through a trocar or cannula for various endoscopic and laparoscopic procedures. As can be appreciated, the overall dimensions of the tool assembly and the elongated shaft are sized accordingly to fit through the trocar or cannula. Alternatively, the presently disclosed staplers may also be designed and/or used for open surgical procedures. The enclosed surgical staplers preferably are suitable for one-handed operation by the user.

It will be understood that various modifications may be made to the embodiments shown herein. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED:

1. A surgical stapler having a distal end onto which a tool assembly having a pair of opposing tissue engaging surfaces can be mounted for deforming a plurality of surgical fasteners through and fasten tissue, the surgical stapler comprising:

a housing having a fixed handle;

a clamping handle mounted to said housing and selectively movable relative to said fixed handle from a first position in spaced relation relative to said fixed handle to a second position closer to said fixed handle to actuate the clamping of tissue;

an adapter yoke which translates within said housing upon actuation of said clamping handle, said adapter yoke mechanically cooperating with a lead screw to actuate the tool assembly to clamp tissue;

a drive assembly including a shaft, said shaft being mechanically engaged with said lead screw such that upon selective activation of said drive assembly, said shaft rotates said lead screw to advance a roll nut distally along said lead screw to force a firing piston into a tool assembly when mounted on the housing to deform the surgical fasteners through and fastening the tissue.

2. A surgical stapler according to claim 1, wherein said drive assembly is pneumatically powered.

3. A surgical stapler according to any preceding claim, wherein said drive assembly is selectively variable to regulate the advancement of said roll nut along said lead screw which, in turn, regulates the speed at which said surgical fasteners are deformed.
4. A surgical stapler according to any preceding claim, wherein said stapler further comprises a pressure sensitive trigger which regulates the advancement of said roll nut along said lead screw which, in turn, regulates the speed at which said surgical fasteners are deformed.
5. A surgical stapler according to any preceding claim, wherein said stapler includes at least one safety which prevents activation of said drive assembly until said safety is deactivated.
6. A surgical stapler according to any preceding claim, wherein said at least one safety is automatically deactivated when said clamping handle is moved to said second position to clamp tissue.
7. A surgical stapler according to any preceding claim, wherein said roll nut includes a firing safety which prevents said roll nut from advancing to force said firing piston until said firing safety is deactivated.

8. A surgical stapler according to any preceding claim, wherein said stapler includes a switch for reversing the rotation of said shaft of said drive assembly upon activation thereof.

9. A surgical stapler according to any preceding claim, wherein said shaft rotates upon activation of said drive assembly which in turn rotates said lead screw.

10. A surgical stapler, comprising:

a housing;

an elongated member attached to the housing;

a tool assembly attachable to the distal end of the elongated member, said tool assembly including an anvil assembly and a cartridge assembly each having an opposing tissue engaging surface, said cartridge assembly including a plurality of surgical fasteners;

a selectively activateable drive assembly including an actuation shaft, said actuation shaft being mechanically engaged with a lead screw such that upon selective activation of said drive assembly, said actuation shaft rotates said lead screw to advance a firing shaft and actuate said tool assembly to initially clamp tissue between opposing tissue engaging surfaces of said tool assembly and subsequently to force a firing piston into said tool assembly to deform the surgical fasteners through and fasten tissue.

11. A surgical stapler according to claim 10, wherein said actuation shaft reciprocates upon activation of said drive assembly, said actuation shaft being mechanically engaged with a converter which converts the reciprocal motion of said actuation shaft into rotary motion of said lead screw.
12. A surgical stapler according to claim 10, wherein said actuation shaft rotates upon activation of said drive assembly which in turn rotates said lead screw.
13. A surgical stapler according to claim 10, 11 or 12, wherein said stapler further comprises a pressure sensitive trigger which regulates the speed of drive assembly which, in turn, regulates the speed at which said surgical fasteners are deformed.
14. A surgical stapler according to claim 10, 11, 12 or 13, wherein said stapler further comprises a switch for reversing the rotation of said shaft of said drive assembly upon activation thereof.
15. A surgical stapler according to any preceding claim, wherein said stapler further comprises a canister for containing a supply of pressurized gas for activation of said drive assembly, said canister being internally disposed within said housing.
16. A surgical stapler according to any preceding claim, wherein said canister is selectively replaceable.

17. A surgical stapler according to any preceding claim, wherein said elongated member and said tool assembly are configured for endoscopic use.

18. A surgical stapler according to any preceding claim, wherein the surgical stapler is suitable for one-handed operation.

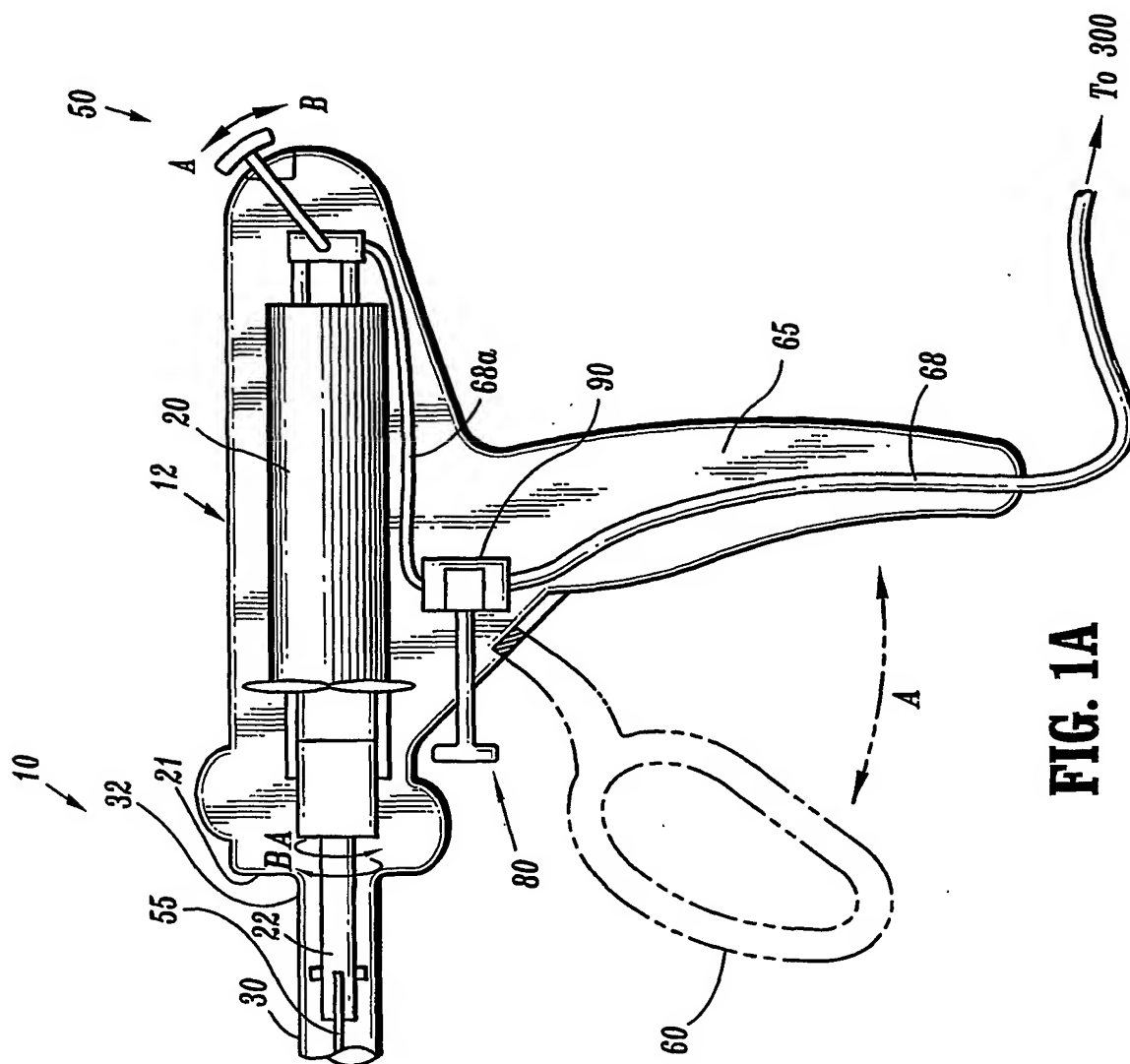


FIG. 1A

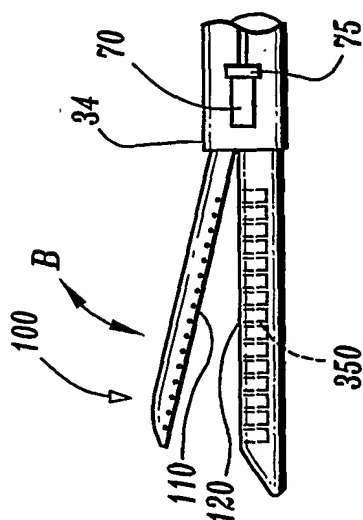
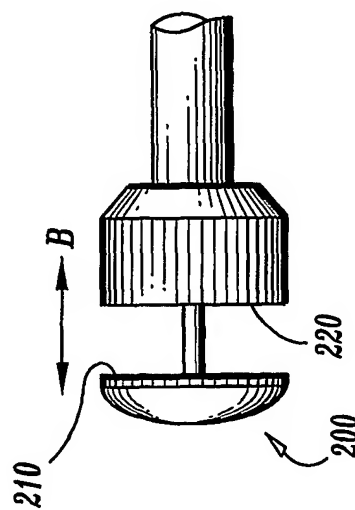


FIG. 1B



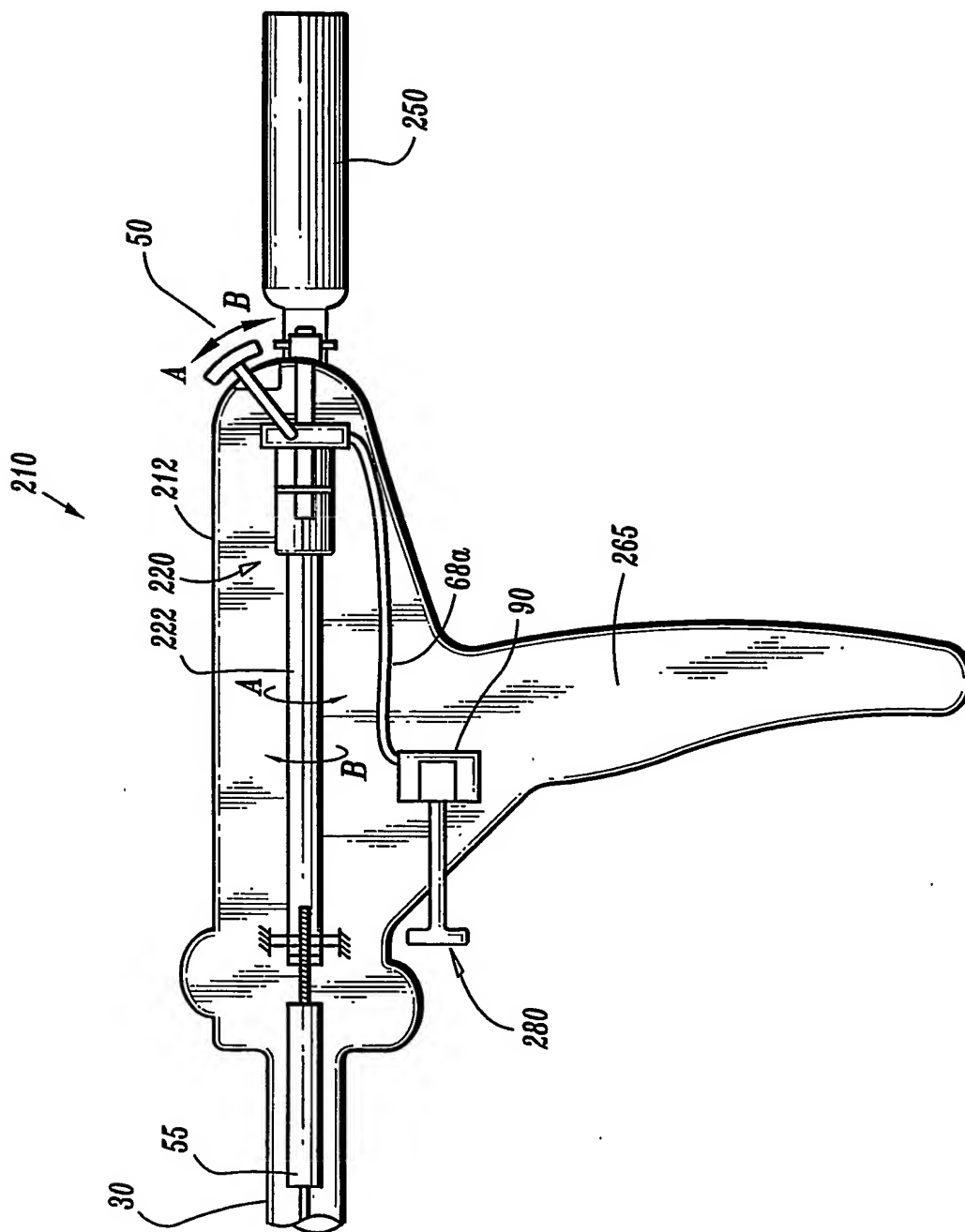
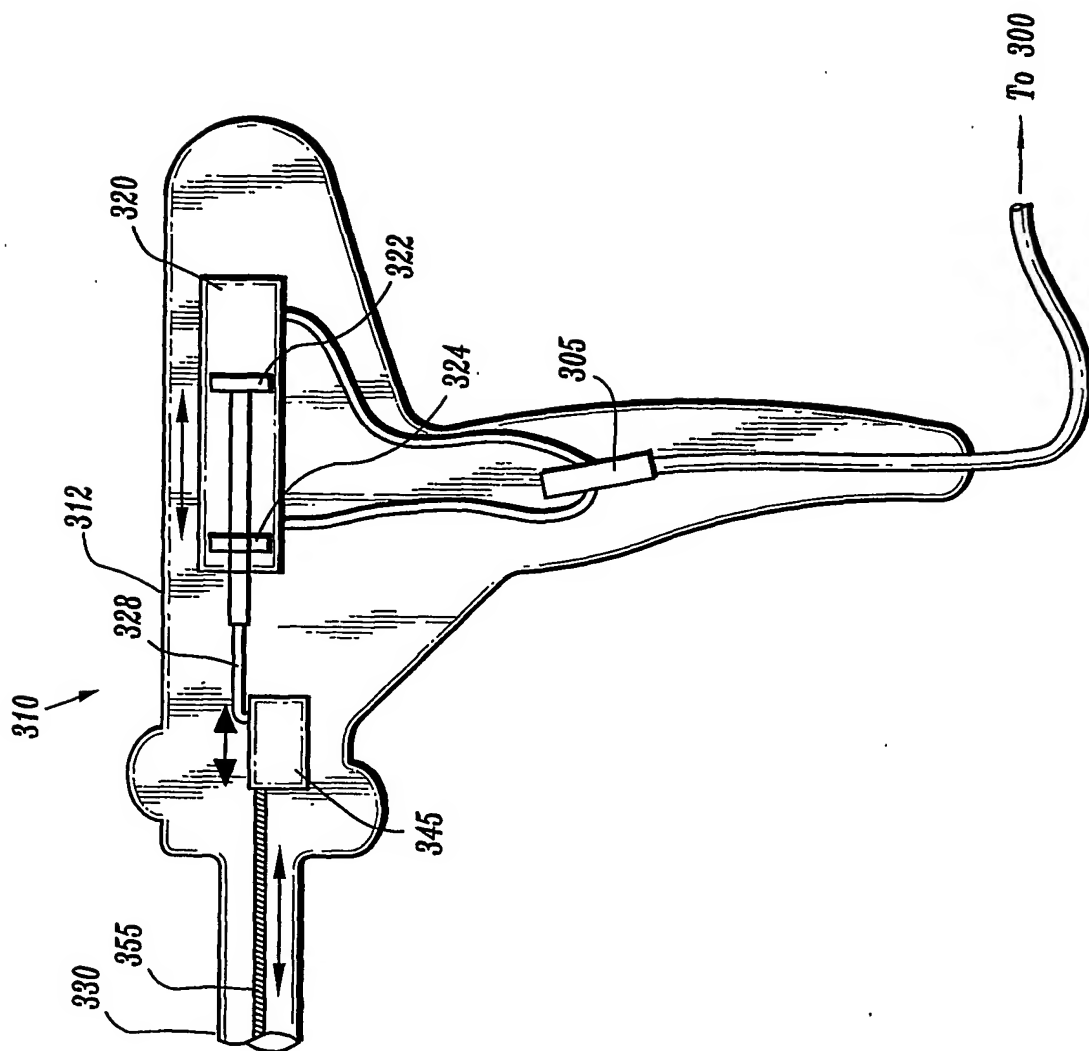
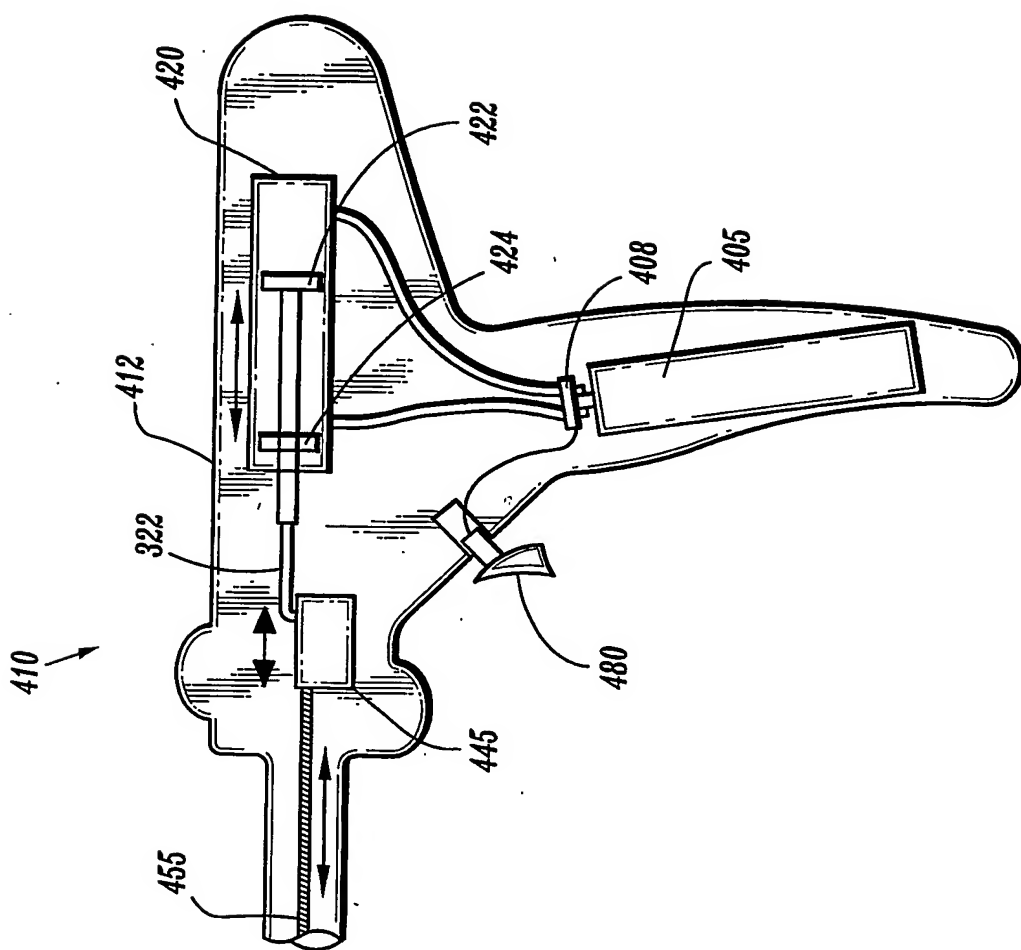


FIG. 2

**FIG. 3**

**FIG. 4**

5/7

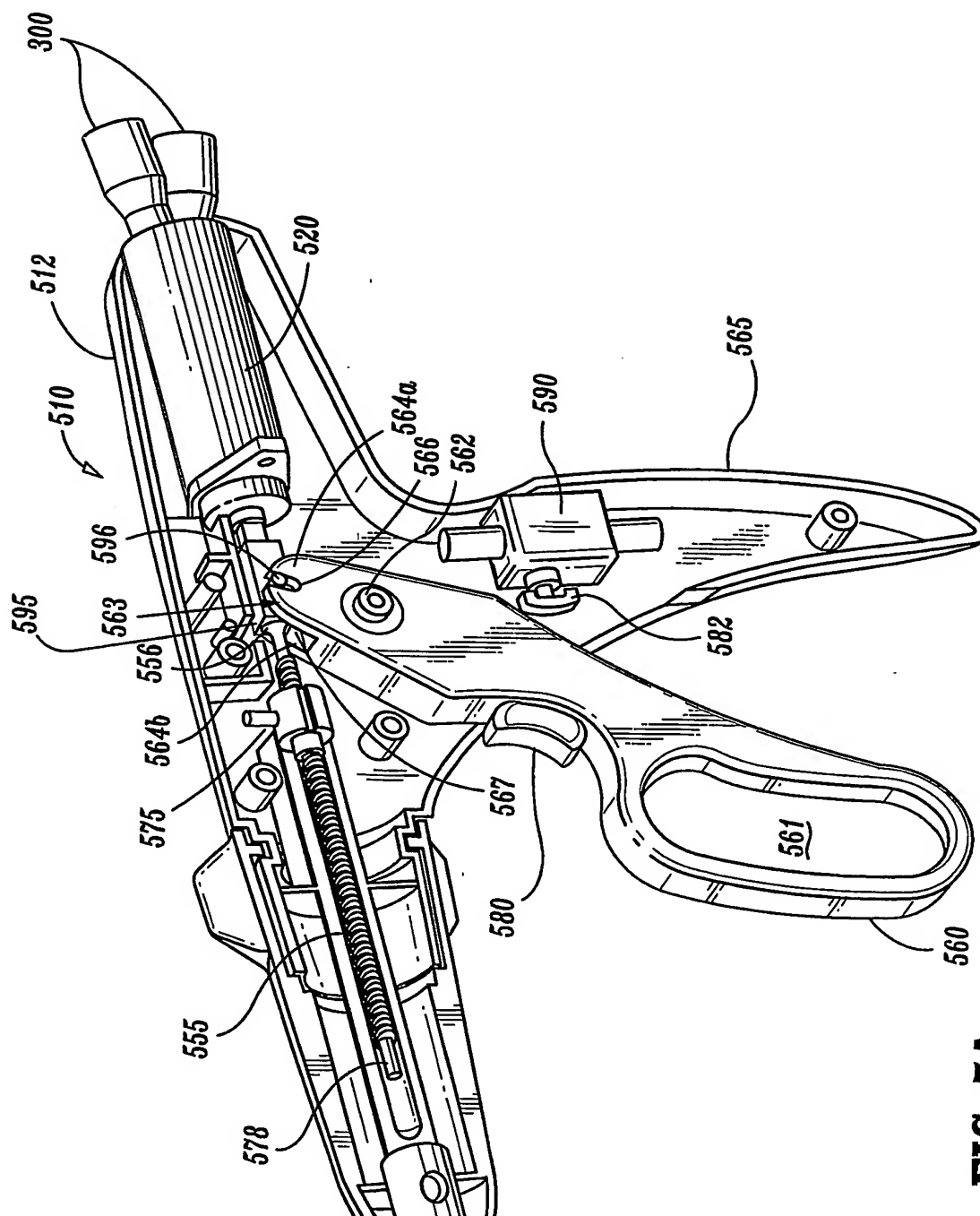


FIG. 5A

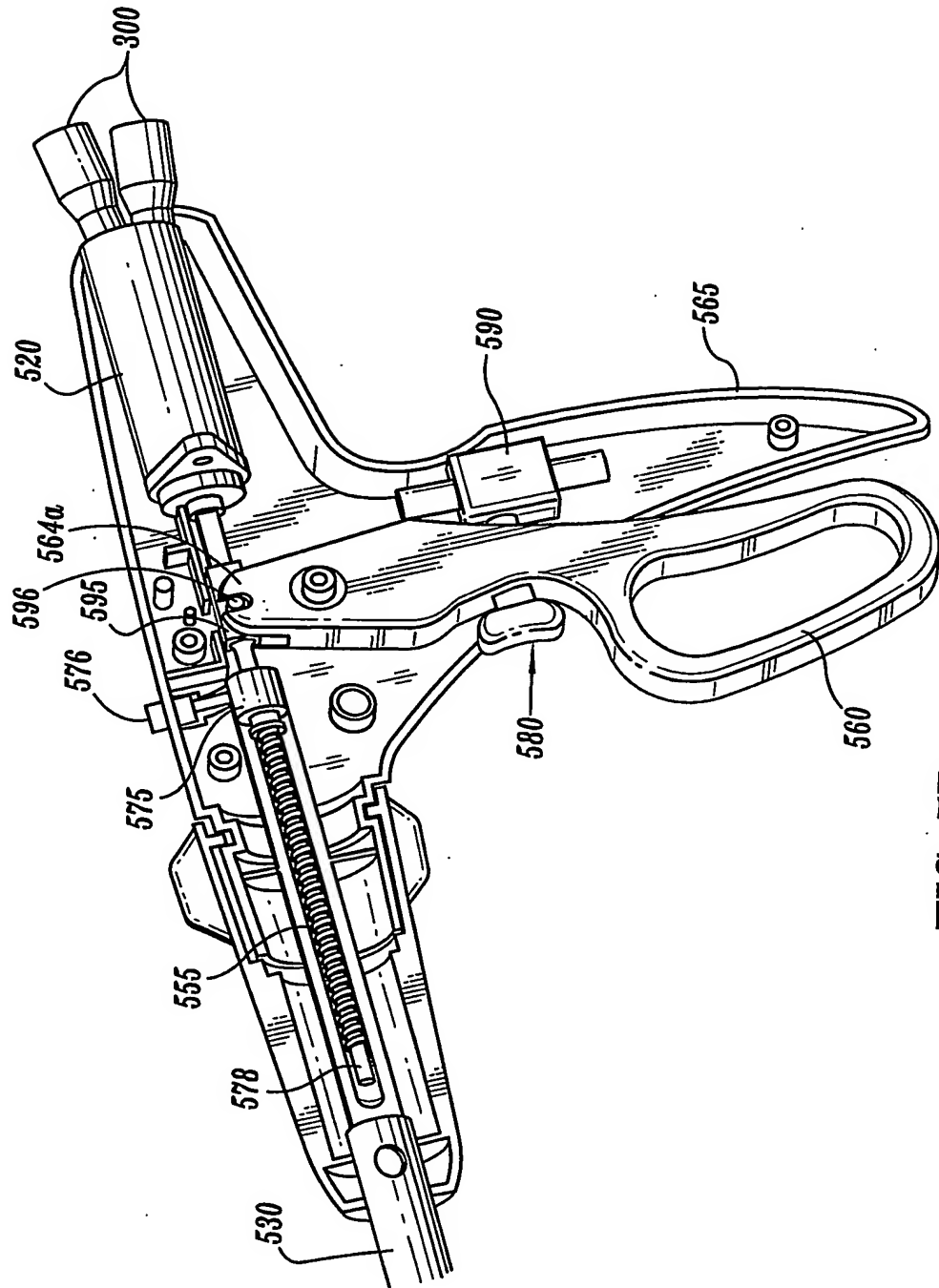


FIG. 5B

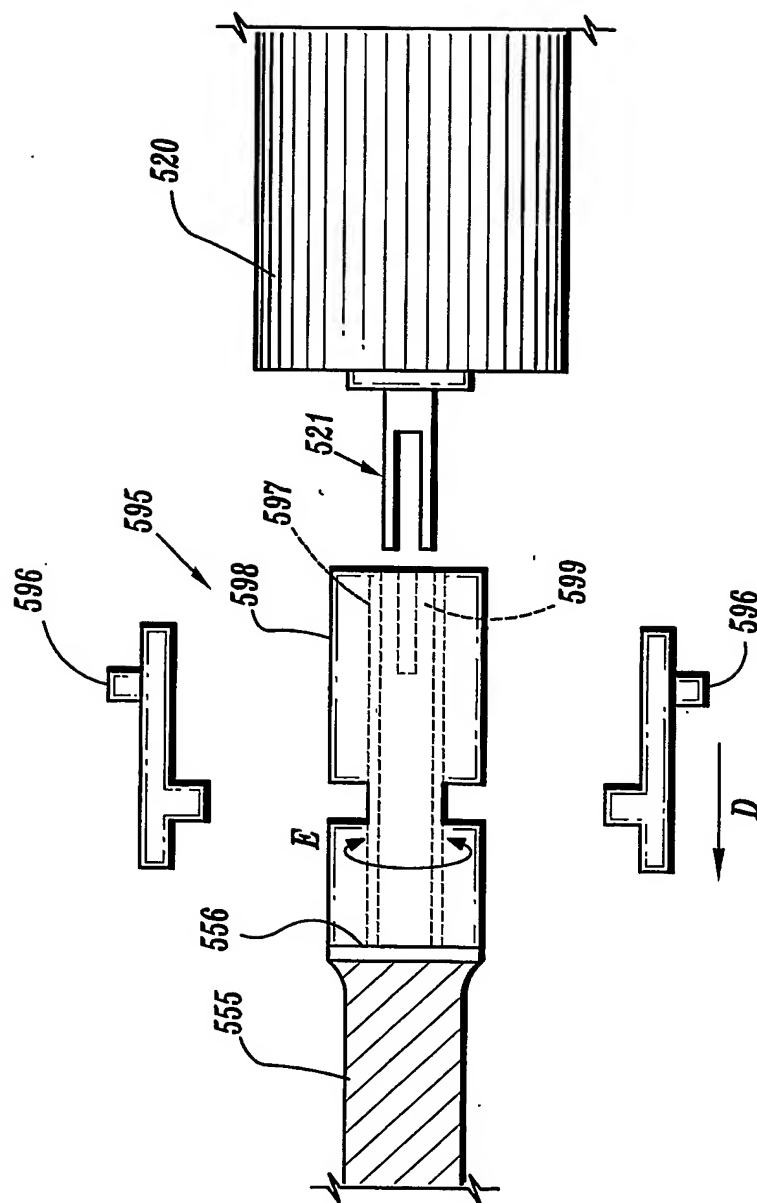


FIG. 6

INTERNATIONAL SEARCH REPORT

Application No
PCT/US 03/31651A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/068

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 667 517 A (HOOVEN MICHAEL DAWSON) 16 September 1997 (1997-09-16)	10
Y	column 5, line 9 - column 6, line 47	11
A	-----	1,3-9
A	US 5 647 526 A (MCCLURE RICHARD C ET AL) 15 July 1997 (1997-07-15)	1-7,15, 16
	column 36, line 34 - column 37, line 47	
A	-----	
A	US 5 782 397 A (KOUKLINE ALEXANDRE) 21 July 1998 (1998-07-21)	1
	column 16, line 32 - line 44	
Y	-----	
Y	US 3 662 939 A (BRYAN GRAHAM W) 16 May 1972 (1972-05-16)	11
	column 8, line 34 - column 9, line 28; figure 9	

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

11 May 2004

Date of mailing of the international search report

26. 05. 2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Angeli, M

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/31651

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-10,12,13-16

A surgical stapler comprising an adapter yoke and a drive shaft, both mechanically cooperating with a lead screw.

2. claim: 11

A surgical stapler comprising a converter for converting reciprocal motion of an actuation shaft into a rotary motion of a lead screw.

INTERNATIONAL SEARCH REPORT

Information on patent family members

In Application No

PCT/US 03/31651

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5667517	A	16-09-1997	
		US 5383880 A	24-01-1995
		US 5518163 A	21-05-1996
		US 5518164 A	21-05-1996
		AT 192639 T	15-05-2000
		AU 670051 B2	04-07-1996
		AU 3117893 A	22-07-1993
		CA 2087221 A1	18-07-1993
		DE 69328576 D1	15-06-2000
		DE 69328576 T2	04-01-2001
		DK 552050 T3	07-08-2000
		EP 0552050 A2	21-07-1993
		ES 2146216 T3	01-08-2000
		GR 1001562 B	29-04-1994
		JP 6007357 A	18-01-1994
		PT 552050 T	31-08-2000
		US 5433721 A	18-07-1995
US 5647526	A	15-07-1997	
		US 5478003 A	26-12-1995
		US 5312023 A	17-05-1994
		US 5326013 A	05-07-1994
		CA 2131975 A1	09-04-1995
		DE 69407916 D1	19-02-1998
		DE 69407916 T2	28-05-1998
		EP 0648476 A1	19-04-1995
		ES 2111228 T3	01-03-1998
		US 5645209 A	08-07-1997
		AU 671292 B2	22-08-1996
		AU 4757793 A	14-04-1994
		CA 2103969 A1	24-03-1994
		CA 2191494 A1	24-03-1994
		DE 69322241 D1	07-01-1999
		DE 69322241 T2	20-05-1999
		EP 0603472 A2	29-06-1994
		ES 2123603 T3	16-01-1999
		JP 6189969 A	12-07-1994
		US 2002096550 A1	25-07-2002
		US 5711472 A	27-01-1998
		US 6250532 B1	26-06-2001
		US 2004050902 A1	18-03-2004
		US 2001030219 A1	18-10-2001
		US 5456401 A	10-10-1995
		US 5482197 A	09-01-1996
		AU 657364 B2	09-03-1995
		AU 2611792 A	22-04-1993
		CA 2080160 A1	19-04-1993
		CA 2426279 A1	19-04-1993
		DE 69223937 D1	12-02-1998
		DE 69223937 T2	28-05-1998
		DE 552423 T1	25-11-1993
		EP 0552423 A2	28-07-1993
		ES 2042445 T1	16-12-1993
		JP 3332965 B2	07-10-2002
		JP 5200038 A	10-08-1993
		US 5397046 A	14-03-1995
		US 5364001 A	15-11-1994
		US 5431322 A	11-07-1995
		US 5472132 A	05-12-1995
		US 5584425 A	17-12-1996

INTERNATIONAL SEARCH REPORT

Information on patent family members

Application No

PCT/US 03/31651

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5647526	A	US 5636780 A	10-06-1997
US 5782397	A	AU 1558995 A	01-08-1995
	21-07-1998	WO 9518572 A1	13-07-1995
US 3662939	A	16-05-1972	NONE